SENATE AMENDMENTS

2nd Printing

By: Thompson of Harris H.B. No. 2561

A BILL TO BE ENTITLED

| 1 | AN ACT |
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| 2 | relating to the continuation and functions of the Texas State Board |
| 3 | of Pharmacy; authorizing a reduction in fees. |
| 4 | BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS: |
| 5 | SECTION 1. Section $481.074(q)$, Health and Safety Code, is |
| 6 | amended to read as follows: |
| 7 | (q) Each dispensing pharmacist shall send all required |
| 8 | information, including any information required to complete the |
| 9 | Schedule III through V prescription forms, to the board by |
| 10 | electronic transfer or another form approved by the board not later |
| 11 | than the <u>next business</u> [seventh] day after the date the |
| 12 | prescription is completely filled. |
| 13 | SECTION 2. Section 481.075(i), Health and Safety Code, is |
| 14 | amended to read as follows: |
| 15 | (i) Each dispensing pharmacist shall: |
| 16 | (1) fill in on the official prescription form or note |
| 17 | in the electronic prescription record each item of information |
| 18 | given orally to the dispensing pharmacy under Subsection (h) and |
| 19 | the date the prescription is filled, and: |
| 20 | (A) for a written prescription, fill in the |
| 21 | dispensing pharmacist's signature; or |
| 22 | (B) for an electronic prescription, |
| 23 | appropriately record the identity of the dispensing pharmacist in |
| 24 | the electronic prescription record; |

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- 1 (2) retain with the records of the pharmacy for at
- 2 least two years:
- 3 (A) the official prescription form or the
- 4 electronic prescription record, as applicable; and
- 5 (B) the name or other patient identification
- 6 required by Section 481.074(m) or (n); and
- 7 (3) send all required information, including any
- 8 information required to complete an official prescription form or
- 9 electronic prescription record, to the board by electronic transfer
- 10 or another form approved by the board not later than the next
- 11 business [seventh] day after the date the prescription is
- 12 completely filled.
- SECTION 3. Section 481.0761, Health and Safety Code, is
- 14 amended by adding Subsections (h), (i), and (j) to read as follows:
- 15 (h) The board, in consultation with the department and the
- 16 regulatory agencies listed in Section 481.076(a)(1), shall
- 17 identify prescribing practices that may be potentially harmful and
- 18 patient prescription patterns that may suggest drug diversion or
- 19 drug abuse. The board shall determine the conduct that constitutes
- 20 a potentially harmful prescribing pattern or practice and develop
- 21 <u>indicators</u> for levels of prescriber or patient activity that
- 22 suggest a potentially harmful prescribing pattern or practice may
- 23 be occurring or drug diversion or drug abuse may be occurring.
- 24 (i) The board, based on the indicators developed under
- 25 Subsection (h), may send an electronic notification to a dispenser
- or prescriber if the information submitted under Section 481.074(q)
- 27 or 481.075 indicates a potentially harmful prescribing pattern or

- 1 practice may be occurring or drug diversion or drug abuse may be
- 2 occurring.
- 3 (j) The board by rule may develop guidelines identifying
- 4 behavior suggesting a patient is obtaining controlled substances
- 5 that indicate drug diversion or drug abuse is occurring. A
- 6 pharmacist who observes behavior described by this subsection by a
- 7 person who is to receive a controlled substance shall access the
- 8 information under Section 481.076(a)(5) regarding the patient for
- 9 whom the substance is to be dispensed.
- 10 SECTION 4. Subchapter C, Chapter 481, Health and Safety
- 11 Code, is amended by adding Sections 481.0763 and 481.0764 to read as
- 12 follows:
- Sec. 481.0763. DUTY OF PHARMACISTS. A pharmacist must
- 14 access information under Section 481.076(a)(5) with respect to a
- 15 patient before dispensing opioids, benzodiazepines, barbiturates,
- 16 or carisoprodol for the patient.
- Sec. 481.0764. REPORTS OF WHOLESALE DISTRIBUTORS. (a) A
- 18 wholesale distributor shall report to the board the information
- 19 that the distributor is required to report to the Automation of
- 20 Reports and Consolidated Orders System (ARCOS) of the Federal Drug
- 21 Enforcement Administration for the distribution of a controlled
- 22 substance by the distributor to a person in this state. The
- 23 distributor shall report the information to the board in the same
- 24 format and with the same frequency as the information is reported to
- 25 ARCOS.
- 26 (b) Information reported to the board under Subsection (a)
- 27 is confidential and not subject to disclosure under Chapter 552,

- 1 Government Code.
- 2 SECTION 5. Section 551.005, Occupations Code, is amended to
- 3 read as follows:
- 4 Sec. 551.005. APPLICATION OF SUNSET ACT. The Texas State
- 5 Board of Pharmacy is subject to Chapter 325, Government Code (Texas
- 6 Sunset Act). Unless continued in existence as provided by that
- 7 chapter, the board is abolished and this subtitle expires September
- 8 1, 2029 [2017].
- 9 SECTION 6. Chapter 551, Occupations Code, is amended by
- 10 adding Section 551.008 to read as follows:
- 11 Sec. 551.008. CLAIM OR DEFENSE FOR PROHIBITED RULE OR
- 12 POLICY. (a) A person may assert as an affirmative defense in an
- 13 administrative hearing or as a claim or defense in a judicial
- 14 proceeding under Chapter 37, Civil Practice and Remedies Code, that
- 15 <u>a board rule</u>, regulation, or policy, or a penalty imposed by the
- 16 board:
- 17 (1) limits the ability of an applicant for a license or
- 18 for registration under this subtitle to be licensed or registered
- 19 based on a sincerely held religious belief of the applicant; or
- 20 (2) burdens a license holder's or registrant's:
- 21 (A) free exercise of religion, regardless of
- 22 whether the burden is the result of a rule generally applicable to
- 23 <u>all license holders or registrants, as applicable;</u>
- (B) freedom of speech regarding a sincerely held
- 25 religious belief; or
- 26 (C) membership in any religious organization.
- (b) Subsection (a) does not apply to a rule, regulation, or

- 1 policy adopted or a penalty imposed by the board that results in a
- 2 limitation or burden described by Subsection (a) if the rule,
- 3 regulation, policy, or penalty is:
- 4 (1) essential to enforcing a compelling governmental
- 5 purpose; and
- 6 (2) narrowly tailored to accomplish that purpose.
- 7 <u>(c) A person may bring an action for injunctive relief</u>
- 8 against a violation of this section.
- 9 SECTION 7. Section 552.006, Occupations Code, is amended by
- 10 amending Subsection (b) and adding Subsection (d) to read as
- 11 follows:
- 12 (b) The training program must provide the person with
- 13 information regarding:
- 14 (1) the law governing the board's operations;
- 15 <u>(2)</u> [this subtitle and] the programs, functions,
- 16 rules, and budget of the board;
- 17 (3) the scope of and limitations on the rulemaking
- 18 authority of the board;
- (4) $\left[\frac{(2)}{2}\right]$ the results of the most recent formal audit
- 20 of the board;
- 21 $\underline{(5)}$ [$\overline{(3)}$] the requirements of:
- 22 <u>(A)</u> laws relating to open meetings, public
- 23 information, administrative procedure, and <u>disclosing</u> conflicts of
- 24 interest; and
- 25 (B) other laws applicable to members of the board
- 26 in performing their duties; and
- (6) $\left[\frac{(4)}{(4)}\right]$ any applicable ethics policies adopted by

- 1 the board or the Texas Ethics Commission.
- 2 <u>(d) The executive director shall create a training manual</u>
- 3 that includes the information required by Subsection (b). The
- 4 executive director shall distribute a copy of the training manual
- 5 annually to each board member. On receipt of the training manual,
- 6 each board member shall sign and submit to the executive director a
- 7 statement acknowledging receipt of the training manual. The board
- 8 shall publish a copy of each signed statement on the board's
- 9 Internet website.
- SECTION 8. Section 553.003(b), Occupations Code, is amended
- 11 to read as follows:
- 12 (b) The executive director is a full-time employee of the
- 13 board and shall:
- 14 (1) serve as secretary to the board; [and]
- 15 (2) perform the regular administrative functions of
- 16 the board and any other duty as the board directs; and
- 17 (3) under the direction of the board, perform the
- 18 duties required by this subtitle or designated by the board.
- 19 SECTION 9. Subchapter A, Chapter 554, Occupations Code, is
- 20 amended by adding Section 554.0011 to read as follows:
- 21 Sec. 554.0011. USE OF ALTERNATIVE RULEMAKING AND DISPUTE
- 22 RESOLUTION. (a) The board shall develop a policy to encourage the
- 23 <u>use of:</u>
- 24 (1) negotiated rulemaking procedures under Chapter
- 25 2008, Government Code, for the adoption of board rules; and
- 26 (2) appropriate alternative dispute resolution
- 27 procedures under Chapter 2009, Government Code, to assist in the

- 1 resolution of internal and external disputes under the board's
- 2 jurisdiction.
- 3 (b) The board's procedures relating to alternative dispute
- 4 resolution must conform, to the extent possible, to any model
- 5 guidelines issued by the State Office of Administrative Hearings
- 6 for the use of alternative dispute resolution by state agencies.
- 7 <u>(c) The board shall:</u>
- 8 (1) coordinate the implementation of the policy
- 9 adopted under Subsection (a);
- 10 (2) provide training as needed to implement the
- 11 procedures for negotiated rulemaking or alternative dispute
- 12 resolution; and
- 13 (3) collect data concerning the effectiveness of those
- 14 procedures.
- SECTION 10. Section 558.051(a), Occupations Code, is
- 16 amended to read as follows:
- 17 (a) To qualify for a license to practice pharmacy, an
- 18 applicant for licensing by examination must submit to the board:
- 19 (1) a license fee set by the board; and
- 20 (2) a completed application on a form prescribed by
- 21 the board with satisfactory sworn evidence that the applicant:
- 22 (A) is at least 18 years of age;
- 23 (B) [is of good moral character;
- [(C)] has completed a minimum of a 1,000-hour
- 25 internship or other program that has been approved by the board or
- 26 has demonstrated, to the board's satisfaction, experience in the
- 27 practice of pharmacy that meets or exceeds the board's minimum

- 1 internship requirements;
- 2 (C) [(D)] has graduated and received a
- 3 professional practice degree, as defined by board rule, from an
- 4 accredited pharmacy degree program approved by the board;
- 5 (D) $\left[\frac{E}{E}\right]$ has passed the examination required by
- 6 the board; and
- 7 $\underline{\text{(E)}}$ [(F)] has not had a pharmacist license
- 8 granted by another state restricted, suspended, revoked, or
- 9 surrendered, for any reason.
- 10 SECTION 11. Section 558.101(a), Occupations Code, is
- 11 amended to read as follows:
- 12 (a) To qualify for a license to practice pharmacy, an
- 13 applicant for licensing by reciprocity must:
- 14 (1) submit to the board:
- 15 (A) a reciprocity fee set by the board; and
- 16 (B) a completed application in the form
- 17 prescribed by the board, given under oath;
- 18 (2) [be of good moral character;
- 19 $\left[\frac{(3)}{(3)}\right]$ have graduated and received a professional
- 20 practice degree, as defined by board rule, from an accredited
- 21 pharmacy degree program approved by the board;
- 22 $\underline{(3)}$ [$\underline{(4)}$] have presented to the board:
- 23 (A) proof of current or initial licensing by
- 24 examination; and
- 25 (B) proof that the current license and any other
- 26 license granted to the applicant by another state has not been
- 27 restricted, suspended, revoked, or surrendered for any reason; and

- 1 (4) [(5)] pass the Texas Pharmacy Jurisprudence
- 2 examination.
- 3 SECTION 12. Section 559.003, Occupations Code, is amended
- 4 by adding Subsection (f) to read as follows:
- 5 (f) The board may refuse to renew a license to practice
- 6 pharmacy for a license holder who is in violation of a board order.
- 7 SECTION 13. Section 568.002(c), Occupations Code, is
- 8 amended to read as follows:
- 9 (c) An applicant for registration as a pharmacy technician
- 10 or a pharmacy technician trainee must[+
- 11 [(1) be of good moral character; and
- 12 $\left[\frac{(2)}{2}\right]$ submit an application on a form prescribed by
- 13 the board.
- 14 SECTION 14. Section 568.004, Occupations Code, is amended
- 15 to read as follows:
- Sec. 568.004. RENEWAL OF REGISTRATION. (a) The board may
- 17 adopt a system in which the registrations of pharmacy technicians
- 18 and pharmacy technician trainees expire on various dates during the
- 19 year.
- 20 (b) To renew a pharmacy technician registration, the
- 21 registrant must, before the expiration date of the registration:
- 22 (1) pay a renewal fee as determined by the board under
- 23 <u>Section 568.005; and</u>
- 24 (2) comply with the continuing education requirements
- 25 prescribed by the board in accordance with Section 568.0045.
- 26 (c) A person whose pharmacy technician registration has
- 27 been expired for 90 days or less may renew the expired registration

- 1 by paying to the board a renewal fee that is equal to one and
- 2 one-half times the normally required renewal fee for the
- 3 registration.
- 4 (d) A person whose pharmacy technician registration has
- 5 been expired for more than 90 days but less than one year may renew
- 6 the expired registration by paying to the board a renewal fee that
- 7 is equal to two times the normally required renewal fee for the
- 8 registration.
- 9 (e) A person whose pharmacy technician registration has
- 10 been expired for one year or more may not renew the
- 11 registration. The person may register by complying with the
- 12 requirements and procedures for initially registering, including
- 13 the examination requirement.
- 14 (f) The board may refuse to renew a pharmacy technician
- 15 registration for a registrant who is in violation of a board order.
- 16 SECTION 15. Chapter 568, Occupations Code, is amended by
- 17 adding Section 568.0045 to read as follows:
- 18 Sec. 568.0045. RULES RELATING TO CONTINUING EDUCATION. The
- 19 board shall adopt rules relating to the continuing education
- 20 required for pharmacy technicians. The rules must include
- 21 <u>requirements for:</u>
- 22 (1) the number of hours of continuing education;
- 23 (2) the methods for meeting the continuing education
- 24 requirements;
- 25 (3) the approval of continuing education programs;
- 26 (4) reporting completion of continuing education;
- 27 (5) records of completion of continuing education; and

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- 1 (6) board audits to ensure compliance with the
- 2 continuing education requirements.
- 3 SECTION 16. A pharmacist is not required to comply with a
- 4 rule adopted under Section 481.0761(j), Health and Safety Code, as
- 5 added by this Act, before January 1, 2018.
- 6 SECTION 17. Section 481.0763, Health and Safety Code, as
- 7 added by this Act, applies only to a pharmacist who dispenses a
- 8 controlled substance on or after January 1, 2018.
- 9 SECTION 18. (a) Except as provided by Subsection (b) of
- 10 this section, Section 552.006, Occupations Code, as amended by this
- 11 Act, applies to a member of the Texas State Board of Pharmacy
- 12 appointed before, on, or after the effective date of this Act.
- 13 (b) A member of the Texas State Board of Pharmacy who,
- 14 before the effective date of this Act, completed the training
- 15 program required by Section 552.006, Occupations Code, as that law
- 16 existed before the effective date of this Act, is required to
- 17 complete additional training only on subjects added by this Act to
- 18 the training program as required by Section 552.006, Occupations
- 19 Code, as amended by this Act. A board member described by this
- 20 subsection may not vote, deliberate, or be counted as a member in
- 21 attendance at a meeting of the board held on or after December 1,
- 22 2017, until the member completes the additional training.
- 23 SECTION 19. Sections 558.051, 558.101, and 568.002,
- 24 Occupations Code, as amended by this Act, apply only to an
- 25 application for a license to practice pharmacy or for registration
- 26 as a pharmacy technician or pharmacy technician trainee filed on or
- 27 after the effective date of this Act. An application for a license

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- 1 or registration filed before the effective date of this Act is
- 2 governed by the law in effect on the date the application was filed,
- 3 and the former law is continued in effect for that purpose.
- 4 SECTION 20. Section 559.003, Occupations Code, as amended
- 5 by this Act, and Sections 568.004(b), (e), and (f), Occupations
- 6 Code, as added by this Act, apply only to the renewal of a license to
- 7 practice pharmacy or of a pharmacy technician registration on or
- 8 after the effective date of this Act. The renewal of a license or
- 9 registration before that date is governed by the law in effect
- 10 immediately before the effective date of this Act, and the former
- 11 law is continued in effect for that purpose.
- 12 SECTION 21. As soon as practicable after the effective date
- 13 of this Act, the Texas State Board of Pharmacy shall adopt rules to
- 14 reduce the amount of the fees imposed by the board for the renewal
- 15 of an expired pharmacy technician registration to reflect the
- 16 amounts provided for by Sections 568.004(c) and (d), Occupations
- 17 Code, as added by this Act. A pharmacy technician who renews an
- 18 expired registration certificate on or after the effective date of
- 19 this Act shall pay the amount provided for by Section 568.004(c) or
- 20 (d), Occupations Code, as added by this Act, instead of the amount
- 21 provided for under board rules adopted before that date.
- 22 SECTION 22. This Act takes effect September 1, 2017.

No.

By: Van Taylor

Substitute the following for ___.B. No.

By: Van Taylor

A BILL TO BE ENTITLED

1 AN ACT

- 2 relating to the continuation and functions of the Texas State
- 3 Board of Pharmacy; authorizing a reduction in fees.
- BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS: 4
- 5 SECTION 1. Section 481.074(q), Health and Safety Code, is
- 6 amended to read as follows:
- 7 (q) Each dispensing pharmacist shall send all required
- information, including any information required to complete the
- 9 Schedule III through V prescription forms, to the board by
- 10 electronic transfer or another form approved by the board not
- later than the next business [seventh] day after the date the 11
- prescription is completely filled. 12
- 13 SECTION 2. Section 481.075(i), Health and Safety Code, is
- amended to read as follows: 14
- 15 (i) Each dispensing pharmacist shall:
- 16 (1) fill in on the official prescription form or note
- in the electronic prescription record each item of information 17
- 18 given orally to the dispensing pharmacy under Subsection (h) and
- the date the prescription is filled, and: 19
- 20 (A) for a written prescription, fill in the
- 21 dispensing pharmacist's signature; or
- 22 (B) for an electronic prescription,
- appropriately record the identity of the dispensing pharmacist 23
- in the electronic prescription record; 24

- 1 (2) retain with the records of the pharmacy for at
- 2 least two years:
- 3 (A) the official prescription form or the
- 4 electronic prescription record, as applicable; and
- 5 (B) the name or other patient identification
- 6 required by Section 481.074(m) or (n); and
- 7 (3) send all required information, including any
- 8 information required to complete an official prescription form
- 9 or electronic prescription record, to the board by electronic
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- 12 is completely filled.
- SECTION 3. Section 481.0761, Health and Safety Code, is
- 14 amended by adding Subsections (h), (i), and (j) to read as
- 15 follows:
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- 17 regulatory agencies listed in Section 481.076(a)(1), shall
- 18 identify prescribing practices that may be potentially harmful
- 19 and patient prescription patterns that may suggest drug
- 20 diversion or drug abuse. The board shall determine the conduct
- 21 that constitutes a potentially harmful prescribing pattern or
- 22 practice and develop indicators for levels of prescriber or
- 23 patient activity that suggest a potentially harmful prescribing
- 24 pattern or practice may be occurring or drug diversion or drug
- 25 abuse may be occurring.
- 26 (i) The board, based on the indicators developed under
- 27 Subsection (h), may send an electronic notification to a

- 1 dispenser or prescriber if the information submitted under
- 2 Section 481.074(q) or 481.075 indicates a potentially harmful
- 3 prescribing pattern or practice may be occurring or drug
- 4 diversion or drug abuse may be occurring.
- 5 (j) The board by rule may develop guidelines identifying
- 6 behavior suggesting a patient is obtaining controlled substances
- 7 that indicate drug diversion or drug abuse is occurring. A
- 8 pharmacist who observes behavior described by this subsection by
- 9 a person who is to receive a controlled substance shall access
- 10 the information under Section 481.076(a)(5) regarding the
- 11 patient for whom the substance is to be dispensed.
- 12 SECTION 4. Subchapter C, Chapter 481, Health and Safety
- 13 Code, is amended by adding Sections 481.0763 and 481.0764 to
- 14 read as follows:
- Sec. 481.0763. DUTY OF PHARMACISTS. A pharmacist must
- 16 access information under Section 481.076(a)(5) with respect to a
- 17 patient before dispensing opioids, benzodiazepines,
- 18 <u>barbiturates</u>, or carisoprodol for the patient.
- Sec. 481.0764. REPORTS OF WHOLESALE DISTRIBUTORS. (a) A
- 20 wholesale distributor shall report to the board the information
- 21 that the distributor is required to report to the Automation of
- 22 Reports and Consolidated Orders System (ARCOS) of the Federal
- 23 Drug Enforcement Administration for the distribution of a
- 24 controlled substance by the distributor to a person in this
- 25 state. The distributor shall report the information to the
- 26 board in the same format and with the same frequency as the
- 27 <u>information</u> is reported to ARCOS.

2 is confidential and not subject to disclosure under Chapter 552, 3 Government Code. 4 SECTION 5. Section 551.005, Occupations Code, is amended 5 to read as follows: Sec. 551.005. APPLICATION OF SUNSET ACT. The Texas State 6 Board of Pharmacy is subject to Chapter 325, Government Code 7 (Texas Sunset Act). Unless continued in existence as provided by 8 that chapter, the board is abolished and this subtitle expires 9 10 September 1, 2029 [2017]. 11 SECTION 6. Chapter 551, Occupations Code, is amended by 12 adding Section 551.008 to read as follows: 13 Sec. 551.008. CLAIM OR DEFENSE FOR PROHIBITED RULE OR 14 POLICY. (a) A person may assert as an affirmative defense in 15 an administrative hearing or as a claim or defense in a judicial proceeding under Chapter 37, Civil Practice and Remedies Code, 16 17 that a board rule, regulation, or policy, or a penalty imposed 18 by the board: 19 (1) limits the ability of an applicant for a license 20 or for registration under this subtitle to be licensed or 21 registered based on a sincerely held religious belief of the 22 applicant; or 23 (2) burdens a license holder's or registrant's: 24 (A) free exercise of religion, regardless of 25 whether the burden is the result of a rule generally applicable 26 to all license holders or registrants, as applicable;

(B) freedom of speech regarding a sincerely held

(b) Information reported to the board under Subsection (a)

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27

- 1 religious belief; or 2 (C) membership in any religious organization. (b) Subsection (a) does not apply to a rule, regulation, 3 or policy adopted or a penalty imposed by the board that results 4 in a limitation or burden described by Subsection (a) if the 5 6 rule, regulation, policy, or penalty is: 7 (1) essential to enforcing a compelling governmental 8 purpose; and 9
- (2) narrowly tailored to accomplish that purpose.
- 10 (c) Subsection (a) does not apply to any action imposed by
- the board to enforce a minimum standard applicable to the 11
- 12 licensing, practice, or professional conduct of a license holder
- or registrant, as required by a statute or rule of the board. 13
- (d) A person may bring an action for injunctive relief 14
- against a violation of this section. 15
- 16 SECTION 7. Section 552.006, Occupations Code, is amended
- by amending Subsection (b) and adding Subsection (d) to read as 17
- 18 follows:
- 19 (b) The training program must provide the person with
- 20 information regarding:
- 21 the law governing the board's operations; (1)
- 22 (2) [this subtitle and] the programs, functions,
- rules, and budget of the board; 23
- 24 (3) the scope of and limitations on the rulemaking
- 25 authority of the board;
- 26 (4) [(2)] the results of the most recent formal audit
- 27 of the board;

5

1 (5) [(3)] the requirements of: 2 (A) laws relating to open meetings, public 3 information, administrative procedure, and disclosing conflicts of interest; and 5 (B) other laws applicable to members of the 6 board in performing their duties; and 7 (6) $[\frac{4}{4}]$ any applicable ethics policies adopted by 8 the board or the Texas Ethics Commission. 9 (d) The executive director shall create a training manual 10 that includes the information required by Subsection (b). The 11 executive director shall distribute a copy of the training 12 manual annually to each board member. On receipt of the 13 training manual, each board member shall sign and submit to the 14 executive director a statement acknowledging receipt of the 15 training manual. The board shall publish a copy of each signed statement on the board's Internet website. 16 SECTION 8. Section 553.003(b), Occupations Code, 17 is 18 amended to read as follows: 19 (b) The executive director is a full-time employee of the 20 board and shall: 21 (1) serve as secretary to the board; [and] 22 (2) perform the regular administrative functions of 23 the board and any other duty as the board directs; and 24 (3) under the direction of the board, perform the

duties required by this subtitle or designated by the board.

amended by adding Section 554.0011 to read as follows:

SECTION 9. Subchapter A, Chapter 554, Occupations Code, is

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2
    RESOLUTION. (a) The board shall develop a policy to encourage
 3
    the use of:
 4
              (1) negotiated rulemaking procedures under Chapter
 5
    2008, Government Code, for the adoption of board rules; and
              (2) appropriate alternative dispute resolution
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 7
    procedures under Chapter 2009, Government Code, to assist in the
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    resolution of internal and external disputes under the board's
 9
    jurisdiction.
10
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11
    resolution must conform, to the extent possible, to any model
12
    guidelines issued by the State Office of Administrative Hearings
13
    for the use of alternative dispute resolution by state agencies.
14
         (c) The board shall:
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              (1) coordinate the implementation of the policy
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    adopted under Subsection (a);
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              (2) provide training as needed to implement the
18
    procedures for negotiated rulemaking or alternative dispute
19
    resolution; and
20
             (3) collect data concerning the effectiveness of
21
    those procedures.
22
        SECTION 10. Section 558.051(a), Occupations Code,
                                                                is
23
    amended to read as follows:
         (a) To qualify for a license to practice pharmacy, an
24
25
    applicant for licensing by examination must submit to the board:
26
              (1) a license fee set by the board; and
27
              (2) a completed application on a form prescribed by
                                                     17.135.30 EES
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Sec. 554.0011. USE OF ALTERNATIVE RULEMAKING AND DISPUTE

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2
                   (A) is at least 18 years of age;
 3
                   (B) [is of good moral character;
 4
                   [(C)] has completed a minimum of a 1,000-hour
 5
    internship or other program that has been approved by the board
    or has demonstrated, to the board's satisfaction, experience in
 6
 7
    the practice of pharmacy that meets or exceeds the board's
    minimum internship requirements;
 9
                   (C) [\frac{D}{D}] has graduated
                                                and
                                                      received
10
    professional practice degree, as defined by board rule, from an
11
    accredited pharmacy degree program approved by the board;
12
                   (D) [(E)] has passed the examination required by
13
    the board; and
14
                   (E) [\frac{F}{F}] has not had a pharmacist license
15
    granted by another state restricted, suspended, revoked, or
    surrendered, for any reason.
16
17
         SECTION 11. Section 558.101(a), Occupations Code,
18
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19
         (a) To qualify for a license to practice pharmacy,
20
    applicant for licensing by reciprocity must:
21
              (1) submit to the board:
22
                   (A) a reciprocity fee set by the board; and
23
                         completed application in the
                   (B)
                       а
                                                               form
24
    prescribed by the board, given under oath;
25
              (2) [be of good moral character;
26
              [+(3)] have graduated and received a professional
    practice degree, as defined by board rule, from an accredited
27
                                   8
                                                       17.135.30 EES
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the board with satisfactory sworn evidence that the applicant:

1

- 1 pharmacy degree program approved by the board;
- 2 $\underline{(3)}$ [(4)] have presented to the board:
- 3 (A) proof of current or initial licensing by
- 4 examination; and
- 5 (B) proof that the current license and any other
- 6 license granted to the applicant by another state has not been
- 7 restricted, suspended, revoked, or surrendered for any reason;
- 8 and
- 9 $\underline{(4)}$ [$\overline{(5)}$] pass the Texas Pharmacy Jurisprudence
- 10 examination.
- 11 SECTION 12. Section 559.003, Occupations Code, is amended
- 12 by adding Subsection (f) to read as follows:
- (f) The board may refuse to renew a license to practice
- 14 pharmacy for a license holder who is in violation of a board
- 15 order.
- SECTION 13. Section 568.002(c), Occupations Code, is
- 17 amended to read as follows:
- 18 (c) An applicant for registration as a pharmacy technician
- 19 or a pharmacy technician trainee must[:
- 20 [(1) be of good moral character; and
- 21 $\left[\frac{(2)}{2}\right]$ submit an application on a form prescribed by
- 22 the board.
- SECTION 14. Section 568.004, Occupations Code, is amended
- 24 to read as follows:
- Sec. 568.004. RENEWAL OF REGISTRATION. (a) The board may
- 26 adopt a system in which the registrations of pharmacy
- 27 technicians and pharmacy technician trainees expire on various

- 1 dates during the year.
- 2 (b) To renew a pharmacy technician registration, the
- 3 registrant must, before the expiration date of the registration:
- 4 (1) pay a renewal fee as determined by the board
- 5 under Section 568.005; and
- 6 (2) comply with the continuing education requirements
- 7 prescribed by the board in accordance with Section 568.0045.
- 8 (c) A person whose pharmacy technician registration has
- 9 been expired for 90 days or less may renew the expired
- 10 registration by paying to the board a renewal fee that is equal
- 11 to one and one-half times the normally required renewal fee for
- 12 the registration.
- (d) A person whose pharmacy technician registration has
- 14 been expired for more than 90 days but less than one year may
- 15 renew the expired registration by paying to the board a renewal
- 16 <u>fee that is equal to two times the normally required renewal fee</u>
- 17 for the registration.
- (e) A person whose pharmacy technician registration has
- 19 been expired for one year or more may not renew the
- 20 registration. The person may register by complying with the
- 21 requirements and procedures for initially registering, including
- 22 the examination requirement.
- 23 (f) The board may refuse to renew a pharmacy technician
- 24 registration for a registrant who is in violation of a board
- 25 <u>order.</u>
- 26 SECTION 15. Chapter 568, Occupations Code, is amended by
- 27 adding Section 568.0045 to read as follows:

10

Sec. 568.0045. RULES RELATING TO CONTINUING EDUCATION. 2 The board shall adopt rules relating to the continuing education 3 required for pharmacy technicians. The rules must include 4 requirements for: 5 (1) the number of hours of continuing education; 6 (2) the methods for meeting the continuing education 7 requirements; 8 (3) the approval of continuing education programs; 9 (4) reporting completion of continuing education; 10 (5) records of completion of continuing education; 11 and (6) board audits to ensure compliance with the 12 13 continuing education requirements. SECTION 16. A pharmacist is not required to comply with a 14 rule adopted under Section 481.0761(j), Health and Safety Code, 15 16 as added by this Act, before January 1, 2018. 17 SECTION 17. Section 481.0763, Health and Safety Code, as added by this Act, applies only to a pharmacist who dispenses a 18 controlled substance on or after January 1, 2018. 19 SECTION 18. (a) Except as provided by Subsection (b) of 20 21 this section, Section 552.006, Occupations Code, as amended by 22 this Act, applies to a member of the Texas State Board of Pharmacy appointed before, on, or after the effective date of 23 24 this Act. (b) A member of the Texas State Board of Pharmacy who, 25 26 before the effective date of this Act, completed the training

program required by Section 552.006, Occupations Code, as that

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1

27

- 1 law existed before the effective date of this Act, is required
- 2 to complete additional training only on subjects added by this
- 3 Act to the training program as required by Section 552.006,
- 4 Occupations Code, as amended by this Act. A board member
- 5 described by this subsection may not vote, deliberate, or be
- 6 counted as a member in attendance at a meeting of the board held
- 7 on or after December 1, 2017, until the member completes the
- 8 additional training.
- 9 SECTION 19. Sections 558.051, 558.101, and 568.002,
- 10 Occupations Code, as amended by this Act, apply only to an
- 11 application for a license to practice pharmacy or for
- 12 registration as a pharmacy technician or pharmacy technician
- 13 trainee filed on or after the effective date of this Act. An
- 14 application for a license or registration filed before the
- 15 effective date of this Act is governed by the law in effect on
- 16 the date the application was filed, and the former law is
- 17 continued in effect for that purpose.
- SECTION 20. Section 559.003, Occupations Code, as amended
- 19 by this Act, and Sections 568.004(b), (e), and (f), Occupations
- 20 Code, as added by this Act, apply only to the renewal of a
- 21 license to practice pharmacy or of a pharmacy technician
- 22 registration on or after the effective date of this Act. The
- 23 renewal of a license or registration before that date is
- 24 governed by the law in effect immediately before the effective
- 25 date of this Act, and the former law is continued in effect for
- 26 that purpose.
- 27 SECTION 21. As soon as practicable after the effective 12 17.135.30 EES

- 1 date of this Act, the Texas State Board of Pharmacy shall adopt
- 2 rules to reduce the amount of the fees imposed by the board for
- 3 the renewal of an expired pharmacy technician registration to
- 4 reflect the amounts provided for by Sections 568.004(c) and (d),
- 5 Occupations Code, as added by this Act. A pharmacy technician
- 6 who renews an expired registration certificate on or after the
- 7 effective date of this Act shall pay the amount provided for by
- 8 Section 568.004(c) or (d), Occupations Code, as added by this
- 9 Act, instead of the amount provided for under board rules
- 10 adopted before that date.

* i 16

11 SECTION 22. This Act takes effect September 1, 2017.



Latary Loans
Secretary of the Senate

Van Taylor BY:

| 1 | Amend C.S.H.B. No. 2561 (senate committee report) as |
|----|---|
| 2 | follows: |
| 3 | (1) In SECTION 7 of the bill, in amended Section 552.006(b), |
| 4 | Occupations Code (page 3, between lines 18 and 19), insert the |
| 5 | following appropriately numbered subdivision: |
| 6 | (_) the types of board rules, interpretations, and |
| 7 | enforcement actions that may implicate federal antitrust law by |
| 8 | limiting competition or impacting prices charged by persons engaged |
| 9 | in a profession or business the board regulates, including rules, |
| 10 | interpretations, and enforcement actions that: |
| 11 | (A) regulate the scope of practice of persons in |
| 12 | a profession or business the board regulates; |
| 13 | (B) restrict advertising by persons in a |
| 14 | profession or business the board regulates; |
| 15 | (C) affect the price of goods or services |
| 16 | provided by persons in a profession or business the board |
| 17 | regulates; and |
| 18 | (D) restrict participation in a profession or |
| 19 | business the board regulates; |
| 20 | (2) Renumber subsequent subdivisions of amended Section |
| 21 | 552.006(b), Occupations Code, appropriately. |

ADOPTED

MAY 2 4 2017

Secretary of the Senate

FLOOR AMENDMENT NO. 🗸

By full

Amend H.B. No. 2561 (senate committee report) by striking added Section 551.008, Occupations Code (page 2, line 49 through page 3 line 8), and replacing it with the following:

Sec. 551.008. PROHIBITION ON RULE VIOLATING SINCERELY HELD RELIGIOUS BELIEF. (a) All rules, regulations, or policies adopted by the board may not violate Chapter 110, Civil Practice and Remedies Code.

(b) A person may assert a violation of Subsection (a) as an affirmative defense in an administrative hearing or as a claim or defense in a judicial proceeding under Chapter 37, Civil Practice and Remedies Code.



FLOOR AMENDMENT NO.

J. Herry-

- Amend C.S.H.B. No. 2561 (senate committee report) as follows:
- (1) In the recital to SECTION 3 of the bill (page 1, line
- 58), strike "(i), and (j)" and substitute "(i), (j), and (k)". 4
- 5 (2) In SECTION 3 of the bill, following added Subsection
- 481.0761(j), Health and Safety Code (page 2, between lines 20 and 6
- 7 21), insert the following:
- (k) The board by rule may develop guidelines identifying 8
- 9 patterns that may indicate that a particular patient to whom a
- controlled substance is prescribed or dispensed is engaging in drug 10
- 11 abuse or drug diversion. These guidelines may be based on the
- frequency of prescriptions issued to and filled by the patient, the 12
- 13 types of controlled substances prescribed, and the number of
- 14 prescribers who prescribe controlled substances to the patient.
- The board may, based on the guidelines developed under this 15
- subsection, send a prescriber or dispenser an electronic 16
- notification if there is reason to believe that a particular 17
- 18 patient is engaging in drug abuse or drug diversion.
- (3) In the recital to SECTION 4 of the bill (page 2, line 19
- 20 22), strike "481.0763 and 481.0764" and substitute "481.0762,
- 21 481.0763, 481.0764, 481.0765, and 481.0766".
- 22 (4) In SECTION 4 of the bill, strike added Section 481.0763,
- Health and Safety Code (page 2, lines 24 through 27), and substitute 23
- 24 the following:
- 25 Sec. 481.0762. MONITORING BY REGULATORY AGENCY. (a) Each
- 26 regulatory agency that issues a license, certification, or
- 27 registration to a prescriber shall promulgate specific guidelines
- 28 for prescribers regulated by that agency for the responsible
- 29 prescribing of opioids, benzodiazepines, barbiturates, or

- 1 carisoprodol.
- 2 (b) A regulatory agency that issues a license,
- 3 certification, or registration to a prescriber shall periodically
- 4 access the information submitted to the board under Sections
- 5 481.074(q) and 481.075 to determine whether a prescriber is
- 6 engaging in potentially harmful prescribing patterns or practices.
- 7 (c) If the board sends a prescriber an electronic
- 8 notification authorized under Section 481.0761(i), the board shall
- 9 immediately send an electronic notification to the appropriate
- 10 regulatory agency.
- 11 (d) In determining whether a potentially harmful
- 12 prescribing pattern or practice is occurring, the appropriate
- 13 regulatory agency, at a minimum, shall consider:
- (1) the number of times a prescriber prescribes
- 15 opioids, benzodiazepines, barbiturates, or carisoprodol; and
- 16 (2) for prescriptions described by Subdivision (1),
- 17 patterns of prescribing combinations of those drugs and other
- 18 dangerous combinations of drugs identified by the board.
- (e) If, during a periodic check under this section, the
- 20 regulatory agency finds evidence that a prescriber may be engaging
- 21 in potentially harmful prescribing patterns or practices, the
- 22 regulatory agency may notify that prescriber.
- (f) A regulatory agency may open a complaint against a
- 24 prescriber if the agency finds evidence during a periodic check
- 25 under this section that the prescriber is engaging in conduct that
- 26 violates this subchapter or any other statute or rule.
- Sec. 481.0763. REGISTRATION BY REGULATORY AGENCY. A
- 28 regulatory agency that issues a license, certification, or
- 29 registration to a prescriber or dispenser shall provide the board
- 30 with any necessary information for each prescriber or dispenser,
- 31 including contact information for the notifications described by

- 1 Sections 481.0761(i) and (k), to register the prescriber or
- 2 dispenser with the system by which the prescriber or dispenser
- 3 receives information as authorized under Section 481.076(a)(5).
- 4 Sec. 481.0764. DUTIES OF PRESCRIBERS, PHARMACISTS, AND
- 5 RELATED HEALTH CARE PRACTITIONERS. (a) A person authorized to
- 6 receive information under Section 481.076(a)(5), other than a
- 7 veterinarian, shall access that information with respect to the
- 8 patient before prescribing or dispensing opioids, benzodiazepines,
- 9 barbiturates, or carisoprodol.
- 10 (b) A person authorized to receive information under
- 11 Section 481.076(a)(5) may access that information with respect to
- 12 the patient before prescribing or dispensing any controlled
- 13 substance.
- (c) A veterinarian authorized to access information under
- 15 Subsection (b) regarding a controlled substance may access the
- 16 information for prescriptions dispensed only for the animals of an
- 17 owner and may not consider the personal prescription history of the
- 18 owner.
- (d) A violation of Subsection (a) is grounds for
- 20 disciplinary action by the regulatory agency that issued a license,
- 21 certification, or registration to the person who committed the
- 22 violation.
- (e) This section does not grant a person the authority to
- 24 <u>issue prescriptions for or dispense controlled substances.</u>
- Sec. 481.0765. EXCEPTIONS. (a) A prescriber is not subject
- 26 to the requirements of Section 481.0764(a) if:
- 27 (1) the patient has been diagnosed with cancer or the
- 28 patient is receiving hospice care; and
- (2) the prescriber clearly notes in the prescription
- 30 record that the patient was diagnosed with cancer or is receiving
- 31 hospice care, as applicable.

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1 (b) A dispenser is not subject to the requirements of
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- 2 Section 481.0764(a) if it is clearly noted in the prescription
- 3 record that the patient has been diagnosed with cancer or is
- 4 receiving hospice care.
- 5 (c) A prescriber or dispenser is not subject to the
- 6 requirements of Section 481.0764(a) and a dispenser is not subject
- 7 to a rule adopted under Section 481.0761(j) if the prescriber or
- 8 dispenser makes a good faith attempt to comply but is unable to
- 9 access the information under Section 481.076(a)(5) because of
- 10 circumstances outside the control of the prescriber or dispenser.
- 11 (5) In SECTION 4 of the bill, in the heading to added Section
- 12 481.0764, Health and Safety Code (page 2, line 28), strike
- 13 "481.0764" and substitute "481.0766".
- 14 (6) Strike SECTION 17 of the bill (page 5, lines 30 through
- 15 32) and substitute the following appropriately numbered SECTION:
- SECTION ____. Section 481.0764(a), Health and Safety Code,
- 17 as added by this Act, applies only to:
- 18 (1) a prescriber other than a veterinarian who issues
- 19 a prescription for a controlled substance on or after September 1,
- 20 2019; or
- (2) a person authorized by law to dispense a
- 22 controlled substance other than a veterinarian who dispenses a
- 23 controlled substance on or after September 1, 2019.
- 24 (7) Add the following appropriately numbered SECTIONS to
- 25 the bill and renumber subsequent sections of the bill accordingly:
- SECTION ____. Section 481.003(a), Health and Safety Code,
- 27 is amended to read as follows:
- 28 (a) The director may adopt rules to administer and enforce
- 29 this chapter, other than Sections 481.073, 481.074, 481.075,
- 30 481.076, [and] 481.0761, 481.0762, 481.0763, 481.0764, 481.0765,
- 31 and 481.0766. The board may adopt rules to administer Sections

- 1 481.073, 481.074, 481.075, 481.076, [and] 481.0761<u>, 481.0762</u>,
- 2 <u>481.0763</u>, 481.0764, 481.0765, and 481.0766.
- 3 SECTION ____. Sections 481.076(a) and (d), Health and
- 4 Safety Code, are amended to read as follows:
- 5 (a) The board may not permit any person to have access to
- 6 information submitted to the board under Section 481.074(q) or
- 7 481.075 except:
- 8 (1) [an investigator for] the board, the Texas Medical
- 9 Board, the Texas State Board of Podiatric Medical Examiners, the
- 10 State Board of Dental Examiners, the State Board of Veterinary
- 11 Medical Examiners, the Texas Board of Nursing, or the Texas
- 12 Optometry Board for the purpose of:
- (A) investigating a specific license holder; or
- (B) monitoring for potentially harmful
- 15 prescribing or dispensing patterns or practices under Section
- 16 481.0762;
- 17 (2) an authorized officer or member of the department
- 18 or authorized employee of the board engaged in the administration,
- 19 investigation, or enforcement of this chapter or another law
- 20 governing illicit drugs in this state or another state;
- 21 (3) the department on behalf of a law enforcement or
- 22 prosecutorial official engaged in the administration,
- 23 investigation, or enforcement of this chapter or another law
- 24 governing illicit drugs in this state or another state;
- 25 (4) a medical examiner conducting an investigation;
- 26 (5) provided that accessing the information is
- 27 authorized under the Health Insurance Portability and
- 28 Accountability Act of 1996 (Pub. L. No. 104-191) and regulations
- 29 adopted under that Act:
- 30 <u>(A)</u> a pharmacist or a pharmacy technician, as
- 31 defined by Section 551.003, Occupations Code, acting at the

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direction of a pharmacist; or
                    (B) a practitioner who:
2
                         (i) is a physician, dentist, veterinarian,
3
   podiatrist, optometrist, or advanced practice nurse or is a
4
   physician assistant described by Section 481.002(39)(D) or an
5
   employee or other agent of a practitioner acting at the direction of
6
   a practitioner; and
7
                         (ii) is inquiring about a recent Schedule
8
   II, III, IV, or V prescription history of a particular patient of
 9
   the practitioner[ - provided that the person accessing the
10
   information is authorized to do so under the Health Insurance
11
   Portability and Accountability Act of 1996 (Pub. L. No. 104-191)
12
    and rules adopted under that Act];
13
               (6) a pharmacist or practitioner who is inquiring
14
    about the person's own dispensing or prescribing activity; or
15
               (7) one or more states or an association of states with
16
    which the board has an interoperability agreement, as provided by
17
    Subsection (j).
18
          (d) Information submitted to the board under this section
19
    may be used only for:
20
               (1) the administration, investigation, or enforcement
21
    of this chapter or another law governing illicit drugs in this state
22
    or another state;
23
                (2) investigatory, [or evidentiary, or monitoring
24
    purposes in connection with the functions of an agency listed in
25
    Subsection (a)(1);
26
                (3) the prescribing and dispensing of controlled
27
    substances by a person listed in Subsection (a)(5); or
28
                (4) [(3)] dissemination by the board to the public in
29
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the form of a statistical tabulation or report if all information

reasonably likely to reveal the identity of each patient,

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31

- 1 practitioner, or other person who is a subject of the information
- 2 has been removed.
- 3 SECTION ____. Section 554.051(a-1), Occupations Code, is
- 4 amended to read as follows:
- 5 (a-1) The board may adopt rules to administer Sections
- 6 481.073, 481.074, 481.075, 481.076, [and] 481.0761, 481.0762,
- 7 481.0763, 481.0764, 481.0765, and 481.0766, Health and Safety Code.
- 8 SECTION ____. (a) A joint interim committee is created to
- 9 conduct an interim study on the monitoring of the prescribing and
- 10 dispensing of controlled substances in this state.
- 11 (b) The joint interim committee shall be composed of three
- 12 senators appointed by the lieutenant governor and three members of
- 13 the house of representatives appointed by the speaker of the house
- 14 of representatives.
- 15 (c) The lieutenant governor and speaker of the house of
- 16 representatives shall each designate a co-chair from among the
- 17 joint interim committee members.
- 18 (d) The joint interim committee shall convene at the joint
- 19 call of the co-chairs.
- 20 (e) The joint interim committee has all other powers and
- 21 duties provided to a special or select committee by the rules of the
- 22 senate and house of representatives, by Subchapter B, Chapter 301,
- 23 Government Code, and by policies of the senate and house committees
- 24 on administration.
- 25 (f) The interim study conducted by the joint interim
- 26 committee must:
- 27 (1) include the number of prescribers and dispensers
- 28 registered to receive information electronically under Section
- 29 481.076, Health and Safety Code, as amended by this Act;
- 30 (2) evaluate the accessing of information under
- 31 Section 481.076, Health and Safety Code, as amended by this Act, by

- 1 regulatory agencies to monitor persons issued a license,
- 2 certification, or registration by those agencies;
- 3 (3) address any complaints, technical difficulties,
- 4 or other issues with electronically accessing and receiving
- 5 information under Section 481.076, Health and Safety Code, as
- 6 amended by this Act;
- 7 (4) examine controlled substance prescribing and
- 8 dispensing trends that may be affected by the passage and
- 9 implementation of this Act;
- 10 (5) evaluate the use and effectiveness of electronic
- 11 notifications sent to prescribers and dispensers under Sections
- 12 481.0761(i) and (k), Health and Safety Code, as added by this Act;
- 13 (6) evaluate the use and effectiveness of identifying
- 14 geographic anomalies in comparing delivery and dispensing data;
- 15 (7) evaluate the integration of any new data elements
- 16 required to be reported under this Act;
- 17 (8) evaluate the existence and scope of diversion of
- 18 controlled substances by animal owners to whom the substances are
- 19 dispensed by veterinarians;
- 20 (9) explore the best methods for preventing the
- 21 diversion of controlled substances by animal owners; and
- 22 (10) determine how any future reporting by dispensing
- 23 veterinarians might best be tailored to fit the practice of
- 24 veterinary medicine.
- 25 (g) The committee shall solicit feedback from regulatory
- 26 agencies, prescribers, dispensers, and patients affected by the
- 27 passage of this Act.
- (h) The committee shall submit a report to the legislature
- 29 on the results of the interim study, including any legislative
- 30 recommendations for improvements to information access and
- 31 controlled substance prescription monitoring, not later than

- 1 January 1, 2019.
- 2 (i) Subject to available resources, the Texas Legislative
- 3 Council shall provide legal and policy research, drafts of proposed
- 4 legislation, and statistical analysis services to the joint interim
- 5 committee for the purpose of the study required under this section.
- 6 (j) Notwithstanding Section 481.076, Health and Safety
 - Code, as amended by this Act, or any other law relating to access to
- 8 or disclosure of prescription drug information maintained by the
- 9 Texas State Board of Pharmacy, the Texas State Board of Pharmacy
- 10 shall disclose any information maintained by the board under
- 11 Section 481.076, Health and Safety Code, to the Texas Legislative
- 12 Council on request of the council for the purpose of assisting with
- 13 the study required under this section.
- 14 (k) Not later than November 1, 2017, the lieutenant governor
- 15 and speaker of the house of representatives shall appoint the
- 16 members of the joint interim committee in accordance with this
- 17 section.
- 18 (1) The joint interim committee created under this section
- 19 is abolished and this section expires January 2, 2019.

FLOOR AMENDMENT NO. 4

MAY 2 4 2017

Actory Secretary of the Senate

Secretary of the Senate

1 Amend Amendment No. by Hinojosa to C.S.H.B. No.

- 2561 (85R32206) by adding the following appropriately numbered 2
- items to the amendment and renumbering subsequent items of the 3
- amendment accordingly: 4
- (__) In the recital to SECTION 6 of the bill, adding 5
- Section 551.008, Occupations Code (page 2, line 48), strike 6
- 7 "Section" and substitute "Sections 551.006 and".
- (__) In SECTION 6 of the bill, immediately before added 8
- Section 551.008, Occupations Code (page 2, between lines 48 and 9
- 10 49), insert the following:
- Sec. 551.006. EXCLUSIVE AUTHORITY. Notwithstanding any 11
- 12 other law, a pharmacist has the exclusive authority to determine
- 13 whether or not to dispense a drug.



floor amendment no.

BY: Charle Ferry

Amend C.S.H.B. No. 2561 (senate committee report) by adding 1 the following appropriately numbered SECTIONS to the bill and 2 renumbering the SECTIONS of the bill accordingly: 3 SECTION ____. Section 562.110, Occupations Code, is amended 4 by amending Subsections (a), (b), (d), (e), and (f) and adding 5 Subsections (g), (h), and (i) to read as follows: 6 (a) In this section: 7 (1) "Provider pharmacy" means a Class A pharmacy that provides pharmacy services through a telepharmacy system at a 9 10 remote dispensing site. (2) "Remote dispensing site" means a location licensed 11 as a telepharmacy that is authorized by a provider pharmacy through 12 a telepharmacy system to store and dispense prescription drugs and 13 devices, including dangerous drugs and controlled substances. 14 (3) "Telepharmacy[Telepharmacy system" means a 15 system that monitors the dispensing of prescription drugs and 16 provides for related drug use review and patient counseling 17 services by an electronic method, including the use of the 18 following types of technology: 19 (A) [(1)] audio and video; 20 (B) $[\frac{(2)}{(2)}]$ still image capture; and 21 (C) $[\frac{(3)}{(3)}]$ store and forward. 22 (b) A Class A or Class C pharmacy located in this state may 23 provide pharmacy services, including the dispensing of drugs, 24 through a telepharmacy system at locations separate from [in a 25 facility that is not at the same location as] the Class A or Class C 26 27 pharmacy. (d) A telepharmacy system may be located only at: 28 (1) a health care facility in this state that is 29

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regulated by this state or the United States; or
 2
                (2) a remote dispensing site.
               The board shall adopt rules regarding the use of a
 3
    telepharmacy system under this section, including:
 4
 5
                (1) the types of health care facilities at which a
    telepharmacy system may be located under Subsection (d)(1), which
 6
 7
    must include the following facilities:
 8
                     (A) a clinic designated as a rural health clinic
    regulated under 42 U.S.C. Section 1395x(aa)[, as amended]; and
 9
                     (B) a health center as defined by 42 U.S.C.
10
11
    Section 254b[ , as amended];
               (2) the locations eligible to be licensed as remote
12
    dispensing sites, which must include locations in medically
13
    underserved areas, areas with a medically underserved population,
14
    and health professional shortage areas determined by the United
15
    States Department of Health and Human Services;
16
               (3) licensing and operating requirements for remote
17
18
    dispensing sites, including:
19
                    (A) a requirement that a remote dispensing site
    license identify the provider pharmacy that will provide pharmacy
20
    services at the remote dispensing site;
21
22
                    (B) a requirement that a provider pharmacy be
    allowed to provide pharmacy services at not more than two remote
23
24
    dispensing sites;
25
                    (C) a requirement that a pharmacist employed by a
   provider pharmacy make at least monthly on-site visits to a remote
26
   dispensing site or more frequent visits if specified by board rule;
27
                    (D) a requirement that each month the perpetual
28
   inventory of controlled substances at the remote dispensing site be
29
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30

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reconciled to the on-hand count of those controlled substances at

the site by a pharmacist employed by the provider pharmacy;

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(E) a requirement that a pharmacist employed by a
1
   provider pharmacy be physically present at a remote dispensing site
2
   when the pharmacist is providing services requiring the physical
3
   presence of the pharmacist, including immunizations;
4
                    (F) a requirement that a remote dispensing site
5
   be staffed by an on-site pharmacy technician who is under the
6
   continuous supervision of a pharmacist employed by the provider
7
8
   pharmacy;
                    (G) a requirement that all pharmacy technicians
9
   at a remote dispensing site be counted for the purpose of
10
   establishing the pharmacist-pharmacy technician ratio of the
11
   provider pharmacy, which, notwithstanding Section 568.006, may not
12
   exceed three pharmacy technicians for each pharmacist providing
13
    supervision;
14
                    (H) a requirement that, before working at a
15
    remote dispensing site, a pharmacy technician must:
16
                         (i) have worked at least one year at a
17
    retail pharmacy during the three years preceding the date the
18
    pharmacy technician begins working at the remote dispensing site;
19
20
    and
                         (ii) have completed a board-approved
2.1
    training program on the proper use of a telepharmacy system;
22
                    (I) a requirement that pharmacy technicians at a
23
    remote dispensing site may not perform extemporaneous sterile or
24
    nonsterile compounding but may prepare commercially available
25
    medications for dispensing, including the reconstitution of orally
26
    administered powder antibiotics; and
27
                    (J) any additional training or practice
28
29
    experience requirements for pharmacy technicians at a remote
    dispensing site;
30
               (4) the areas that qualify under Subsection (f);
31
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- 1 (5) [(3)] recordkeeping requirements; and
- (6) [(4)] security requirements.
- 3 (f) A telepharmacy system <u>located</u> at a health care facility
- 4 under Subsection (d)(1) may not be located in a community in which a
- 5 Class A or Class C pharmacy is located as determined by board rule.
- 6 If a Class A or Class C pharmacy is established in a community in
- 7 which a telepharmacy system has been located under this section,
- 8 the telepharmacy system may continue to operate in that community.
- 9 (g) A telepharmacy system located at a remote dispensing
- 10 site under Subsection (d)(2) may not dispense a controlled
- 11 substance listed in Schedule II as established by the commissioner
- of state health services under Chapter 481, Health and Safety Code,
- and may not be located within 22 miles by road of a Class A pharmacy.
- (h) If a Class A pharmacy is established within 22 miles by
- 15 road of a remote dispensing site that is currently operating, the
- 16 remote dispensing site may continue to operate at that location.
- (i) The board by rule shall require and develop a process
- 18 for a remote dispensing site to apply for classification as a Class
- 19 A pharmacy if the average number of prescriptions dispensed each
- 20 day the remote dispensing site is open for business is more than
- 21 125, as calculated each calendar year.
- 22 SECTION ____. The Texas State Board of Pharmacy shall adopt
- 23 rules under Section 562.110, Occupations Code, as amended by this
- 24 Act, not later than January 1, 2018.

MAY 24 2017

FLOOR AMENDMENT NO.

1

Amend C.S.H.B. No. 2561 (senate committee report) by adding the following appropriately numbered SECTIONS to the bill and 2 renumbering the SECTIONS of the bill accordingly: 3 SECTION ____. (a) Subtitle A, Title 6, Health and Safety 4 Code, is amended by adding Chapter 442 to read as follows: 5 CHAPTER 442. DONATION OF PRESCRIPTION DRUGS 6 7 SUBCHAPTER A. GENERAL PROVISIONS Sec. 442.001. DEFINITIONS. In this chapter: 8 (1) "Donor" means an individual who donates unused 9 prescription drugs under this chapter to a participating provider. 10 (2) "Health care facility" means a facility that 11 provides health care services to patients and maintains a pharmacy 12 in the facility. The term includes the following facilities if a 13 14 pharmacy is maintained in the facility: 15 (A) a general or special hospital as defined by Chapter 241; 16 17 (B) an ambulatory surgical center licensed under 18 Chapter 243; and 19 (C) an institution licensed under Chapter 242. (3) "Health care professional" means an individual 20 licensed, certified, or otherwise authorized to administer health 21 care and prescribe prescription drugs, for profit or otherwise, in 22 the ordinary course of business or professional practice. The term 23 does not include a health care facility. 24 25 (4) "Participating provider" means a health care facility or pharmacy, or a pharmacist who is an employee of the 26 facility or pharmacy, that elects to participate in the collection 27 and redistribution of donated prescription drugs under this 28 29 chapter.

- 1 (5) "Pharmacist" means a person licensed under Chapter
- 2 558, Occupations Code.
- 3 (6) "Pharmacy" means an entity licensed under Chapter
- 4 560, Occupations Code.
- 5 (7) "Prescription drug" has the meaning assigned by
- 6 Section 551.003, Occupations Code.
- 7 (8) "Recipient" means an individual who voluntarily
- 8 receives donated prescription drugs under this chapter.
- 9 (9) "Tamper-evident" means packaging that allows for
- 10 detection of unauthorized access to a prescription drug.
- 11 Sec. 442.002. RULEMAKING AUTHORITY. The executive
- 12 commissioner may adopt rules to implement this chapter.
- 13 Sec. 442.003. CONSTRUCTION WITH OTHER LAW. This chapter
- 14 does not limit the authority of this state or a political
- 15 subdivision of this state to regulate or prohibit a prescription
- 16 drug.
- 17 SUBCHAPTER B. DONATION AND REDISTRIBUTION OF UNUSED PRESCRIPTION
- DRUGS DRUGS
- 19 Sec. 442.051. DONATION AND REDISTRIBUTION OF PRESCRIPTION
- 20 DRUGS. (a) A donor may donate unused prescription drugs to a
- 21 participating provider in accordance with this chapter and rules
- 22 adopted under this chapter.
- 23 (b) A participating provider may dispense donated
- 24 prescription drugs to a recipient in accordance with this chapter
- 25 and rules adopted under this chapter.
- Sec. 442.052. STANDARDS FOR DONATION AND REDISTRIBUTION.
- 27 (a) The executive commissioner by rule shall adopt standards and
- 28 procedures for:
- (1) accepting, storing, labeling, and dispensing
- 30 donated prescription drugs; and
- 31 (2) inspecting donated prescription drugs to

- 1 determine whether the drugs are adulterated and whether the drugs
- 2 are safe and suitable for redistribution.
- 3 (b) In adopting standards and procedures under this
- 4 section, the executive commissioner shall ensure that the donation
- 5 and redistribution process is consistent with public health and
- 6 safety standards.
- 7 Sec. 442.053. REQUIREMENTS FOR DONATED PRESCRIPTION DRUGS.
- 8 (a) A donated prescription drug may be accepted or dispensed under
- 9 this chapter only if the drug is in its original, unopened, sealed,
- 10 and tamper-evident unit-dose packaging. A drug packaged in single
- 11 unit doses may be accepted and dispensed if the outside packaging is
- 12 opened but the single unit-dose packaging is unopened.
- (b) A donated prescription drug may not be accepted or
- 14 <u>dispensed under this chapter if:</u>
- (1) the drug is a controlled substance;
- 16 (2) the drug is adulterated or misbranded;
- 17 (3) the drug is not stored in compliance with the
- 18 drug's product label; or
- (4) the United States Food and Drug Administration
- 20 requires the drug to have a risk evaluation or mitigation strategy.
- (c) A participating provider shall comply with all
- 22 applicable provisions of state and federal law relating to the
- 23 inspection, storage, labeling, and dispensing of prescription
- 24 drugs.
- Sec. 442.054. DONATION PROCESS. (a) Before being
- 26 dispensed to a recipient, a prescription drug donated under this
- 27 chapter must be inspected by the participating provider in
- 28 accordance with federal law, laws of this state, and department
- 29 rule to determine whether the drug is adulterated or misbranded and
- 30 whether the drug has been stored in compliance with the
- 31 requirements of the product label.

- 1 (b) A donated prescription drug dispensed to a recipient
- 2 under this chapter must be prescribed by a health care professional
- 3 for use by the recipient.
- 4 (c) A participating provider may charge a handling fee not
- 5 to exceed \$20 to a recipient to cover the costs of inspecting,
- 6 storing, labeling, and dispensing the donated prescription drug. A
- 7 participating provider may not resell a prescription drug donated
- 8 under this chapter. A donor may not sell a prescription drug to a
- 9 participating provider.
- 10 (d) A participating provider may not submit a claim or
- 11 otherwise seek reimbursement from any public or private third-party
- 12 payor for donated prescription drugs dispensed to a recipient under
- 13 this chapter. A public or private third-party payor is not required
- 14 to provide reimbursement for donated drugs dispensed to a recipient
- 15 under this chapter.
- Sec. 442.055. DONOR FORM. Before donating a prescription
- 17 drug under this chapter, a donor shall sign a form prescribed by the
- 18 department stating that:
- (1) the donor is the owner of the donated prescription
- 20 drug;
- 21 (2) the donated prescription drug has been properly
- 22 stored and the container has not been opened or tampered with;
- 23 (3) the donated prescription drug has not been
- 24 adulterated or misbranded; and
- 25 (4) the donor is voluntarily donating the prescription
- 26 drug.
- Sec. 442.056. RECIPIENT FORM. Before accepting a donated
- 28 prescription drug under this chapter, a recipient shall sign a form
- 29 prescribed by the department stating that:
- 30 (1) the recipient acknowledges that the donor is not a
- 31 pharmacist and the donor took ordinary care of the prescription

- 1 drug;
- 2 (2) the recipient acknowledges that the donor is known
- 3 to the participating provider and that there is no reason to believe
- 4 that the prescription drug was improperly handled or stored;
- 5 (3) by accepting the prescription drug, the recipient
- 6 accepts any risk that an accidental mishandling could create; and
- 7 (4) the recipient releases the donor, participating
- 8 provider, and manufacturer of the drug from liability related to
- 9 the prescription drug.
- Sec. 442.057. LIMITATION OF LIABILITY. (a) A donor or
- 11 participating provider who acts in good faith in donating,
- 12 accepting, storing, labeling, distributing, or dispensing
- 13 prescription drugs under this chapter:
- (1) is not criminally liable and is not subject to
- 15 professional disciplinary action for those activities; and
- 16 (2) is not civilly liable for damages for bodily
- injury, death, or property damage that arises from those activities
- 18 unless the injury, death, or damage arises from the donor or
- 19 participating provider's recklessness or intentional conduct.
- (b) A manufacturer of a prescription drug that donates a
- 21 drug under this chapter is not, in the absence of bad faith,
- 22 criminally or civilly liable for bodily injury, death, or property
- 23 damage arising from the donation, acceptance, or dispensing of the
- 24 drug, including the manufacturer's failure to communicate to a
- 25 donor or other person:
- (1) product or consumer information about the donated
- 27 prescription drug; or
- (2) the expiration date of the donated prescription
- 29 drug.
- Sec. 442.058. DATABASE OF PARTICIPATING PROVIDERS. The
- 31 department shall establish and maintain an electronic database that

- 1 lists each participating provider. The department shall post the
- 2 database on its Internet website.
- 3 (b) If before implementing any provision of this section a
- 4 state agency determines that a waiver or authorization from a
- 5 federal agency is necessary for implementation of that provision,
- 6 the agency affected by the provision shall request the waiver or
- 7 authorization and may delay implementing that provision until the
- 8 waiver or authorization is granted.
- 9 SECTION ____. Not later than December 1, 2017, the
- 10 executive commissioner of the Health and Human Services Commission
- 11 shall adopt the rules necessary for the implementation of Chapter
- 12 442, Health and Safety Code, as added by this Act.

MAY 2 4 2017

- Amend H.B. No. 2561 by adding the following appropriately 1
- 2 numbered SECTION and renumbering subsequent SECTIONS
- 3 accordingly:
- 4 SECTION ____. Section 89.051(b), Education Code, is
- amended to read as follows: 5
- 6 (b) The college shall be known as The Texas A&M University
- 7 System Health Science Center Irma Lerma Rangel College of
- 8 Pharmacy, and the primary building in which the school is
- 9 operated shall be located in Kleberg County and must include
- 10 "Irma Rangel" in its official name.

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

May 25, 2017

TO: Honorable Joe Straus, Speaker of the House, House of Representatives

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB2561 by Thompson, Senfronia (Relating to the continuation and functions of the Texas State Board of Pharmacy; authorizing a reduction in fees.), As Passed 2nd House

Estimated Two-year Net Impact to General Revenue Related Funds for HB2561, As Passed 2nd House: an impact of \$0 through the biennium ending August 31, 2019.

The bill would make no appropriation but could provide the legal basis for an appropriation of funds to implement the provisions of the bill.

General Revenue-Related Funds, Five-Year Impact:

| Fiscal Year | Probable Net Positive/(Negative) Impact to General Revenue Related Funds | |
|-------------|---|--|
| 2018 | \$0 | |
| 2019 | \$0 | |
| 2020 | \$0 | |
| 2021 | \$0 | |
| 2022 | \$0 | |

| Fiscal Year | Probable Savings/(Cost) from General Revenue Fund 1 | | from Gain/(Loss) from | Change in Number of State Employees from FY 2017 |
|-------------|--|-------------|-----------------------|---|
| 2018 | | (\$307,990) | \$307,990 | 2.0 |
| 2019 | | (\$241,400) | \$241,400 | 2.0 |
| 2020 | | (\$241,400) | \$241,400 | 2.0 |
| 2021 | | (\$241,400) | \$241,400 | 2.0 |
| 2022 | | (\$241,400) | \$241,400 | 2.0 |

The bill would amend the Health and Safety Code relating to the continuation and functions of the Texas State Board of Pharmacy (TSBP); authorizing a reduction in fees. The bill would continue TSBP for twelve years until September 1, 2029.

The bill would require the TSBP, in consultation with the Optometry Board, Texas Medical Board, Texas State Board of Podiatric Medical Examiners, State Board of Dental Examiners, State Board of Veterinary Medical Examiners, and the Texas Board of Nursing, to determine conduct that constitutes abusive prescribing patterns or practices by applicable licensees. Under the provisions of the bill, TSBP would be permitted to send electronic notification to a dispenser or a prescriber if the information submitted to the Prescription Monitoring Program (PMP) indicates harmful prescribing patterns. The bill would require a wholesale distributor to report the same information that is reported to the Automation of Reports and Consolidated Orders System of the Federal Drug Enforcement Administration to TSBP.

The bill would require TSBP to develop a policy to encourage the use of certain negotiated rulemaking and appropriate alternative dispute resolution procedures. Under the provisions of the bill, TSBP would be required to coordinate the implementation of the policy, provide training for implementation of the policy, and collect data on the effectiveness of the procedures.

The bill would permit an applicant or a licensee to assert as an affirmative defense in an administrative hearing or as a claim of defense in a judicial proceeding that a rule, regulation, policy or a penalty imposed by TSBP limits an applicant's exercise of religion or membership in an religious organization. The bill would provide exemptions to certain rules, regulations, policies, or penalties imposed by TSBP. Under the provisions of the bill, a licensee or applicant could bring an action for injunctive relief against a violation.

The bill would modify the renewal fee of a pharmacy technician based on the amount of time from the expiration of the licensee's former license. The bill would require TSBP to adopt rules relating to the continuing education requirements for pharmacy technicians.

The bill would require regulatory agencies, including the Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing and the Board of Podiatric Medical Examiners to periodically access and monitor the Prescription Monitoring Program for prescribing behavior and dispensing patterns of licensees. The bill would allow a regulatory agency to notify a prescriber of potentially harmful behavior and allow for the opening of a complaint by the agency under certain requirements. The bill would require a regulatory agency to provide contact information for applicable licensees to the TSBP and the TSBP would be required to notify the regulatory agency when TSBP notifies a licensee that a potentially harmful prescribing pattern has been indicated. The bill would permit TSBP to send electronic notifications to prescribers and dispensers meeting harmful patterns. The bill would require certain licensees to access prescription history prior to prescribing or dispensing certain substances. The bill provides exceptions.

The bill would specify that a pharmacist has the exclusive authority to determine whether or not to dispense a drug. The bill would require the Texas State Board of Pharmacy (TSBP) to develop a process for a remote dispensing site to apply for classification as a Class A pharmacy.

The bill would authorize, in certain circumstances, the donation of unused prescription drugs and the dispensing of donated drugs. The bill would require the Department of State Health Services (DSHS) to develop a form for donors and recipients participating in the program and establish and

maintain an electronic database of participating providers. Additionally, the bill would require the executive commissioner of the Health and Human Services Commission (HHSC) to adopt rules to implement the program.

The bill would amend the Education Code to require the primary building in which the Texas A&M University System Health Science Center Irma Lerma Rangel College of Pharmacy is operated to be located in Kleberg County.

The bill would take effect on September 1, 2017.

Methodology

The provisions of the bill would result in a cost of \$307,990 in General Revenue in fiscal year 2018 and a cost of \$241,400 in General Revenue in fiscal year 2019 and following fiscal years. This analysis assumes that TSBP would input and track wholesale pharmaceutical distributor reporting in a database.

Based on the analysis of the TBSP, it is assumed the TSBP would require two additional full-time-equivalents (FTEs) to implement provisions of the bill relating to TSBP inputting and tracking wholesale pharmaceutical distributor reporting in a database and monitoring requirements by searching PMP data and providing the information to the other regulatory agencies, including the Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing and the Board of Podiatric Medical Examiners. The additional two FTEs would have an estimated cost to General Revenue of \$149,594 in fiscal year 2018 and \$141,404 each year thereafter. TSBP estimates one-time start up costs of \$8,190 for the additional FTEs and annual costs of \$100,224 in salaries and wages for a Program Specialist III, \$36,701 in employee benefits and other payroll contribution costs, and \$4,480 for other operating expenses.

TSBP also estimates a one-time cost of \$58,400 in General Revenue in fiscal year 2018 for a database to track the additional required information from wholesale pharmaceutical distributors and a PMP upgrade to include contact information for notifications of potentially harmful prescribing or dispensing habits to licensees. In addition to the one-time costs in fiscal year 2018, TSBP estimates an ongoing operating cost of \$99,996 for the database in each fiscal year due to ongoing hosting and data support for the wholesale pharmaceutical distribution information.

This analysis assumes that any increased database cost to the TSBP, which is statutorily required to generate sufficient revenue to cover its costs of operation, would be offset by an increase in fee generated revenue by the agency.

This analysis assumes that any increased Prescription Monitoring Program cost to the TSBP, which is statutorily required to generate sufficient revenue to cover its costs of operation, would be offset by an increase in fee generated revenue by the agency and other regulatory agencies whose licensees are required to access the PMP, including the Board of Veterinary Medical Examiners, Texas State Board of Dental Examiners, Optometry Board, Texas Medical Board, Texas Board of Nursing and the Board of Podiatric Medical Examiners.

The Comptroller of Public Accounts estimates the modification to the renewal fee of a pharmacy technician based on time elapsed since the expiration of the licensee's former license would result in a decrease of approximately \$36,000 in revenue to the General Revenue Fund per fiscal year.

The Department of Public Safety, Department of State Health Services, Health and Human Services Commission, Office of the Attorney General, State Office of Administrative Hearings, Office of Court Administration, Texas A&M University System Administration, Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing, and Texas Board of Podiatric Medical Examiners anticipate any additional work resulting from the passage of the bill could be reasonably absorbed within current resources.

Technology

The costs identified above include estimated one-time information technology costs of \$58,400 in fiscal year 2018 and ongoing costs of \$99,996 for database development to accompany the wholesale distributor reporting requirements and \$2,308 for one-time equipment for the additional FTE at TSBP.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 116 Sunset Advisory Commission, 212 Office of Court Administration,

Texas Judicial Council, 304 Comptroller of Public Accounts, 360 State Office of Administrative Hearings, 515 Board of Pharmacy, 302 Office of the Attorney General, 405 Department of Public Safety, 503 Texas Medical Board, 504 Texas State Board of Dental Examiners, 507 Texas Board of Nursing, 512 Board of Podiatric Medical Examiners, 514

Optometry Board, 578 Board of Veterinary Medical Examiners

LBB Staff: UP, EK, KCA, EH, BRi

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

May 16, 2017

TO: Honorable Charles Schwertner, Chair, Senate Committee on Health & Human Services

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB2561 by Thompson, Senfronia (Relating to the continuation and functions of the Texas State Board of Pharmacy; authorizing a reduction in fees.), Committee Report 2nd House,

Substituted

Estimated Two-year Net Impact to General Revenue Related Funds for HB2561, Committee Report 2nd House, Substituted: an impact of \$0 through the biennium ending August 31, 2019.

The bill would make no appropriation but could provide the legal basis for an appropriation of funds to implement the provisions of the bill.

General Revenue-Related Funds, Five-Year Impact:

| Fiscal Year | Probable Net Positive/(Negative) Impact to General Revenue Related Funds |
|-------------|---|
| 2018 | \$0 |
| 2019 | \$0 |
| 2020 | \$0 |
| 2021 | \$0 |
| 2022 | \$0 |

| Fiscal Year | Probable Savings/(Cost) from <i>General Revenue Fund</i> 1 | Probable Revenue Gain/(Loss) from General Revenue Fund 1 | Change in Number of State Employees from FY 2017 |
|-------------|---|---|---|
| 2018 | (\$224,793) | \$224,793 | 1.0 |
| 2019 | (\$170,698) | \$170,698 | 1.0 |
| 2020 | (\$170,698) | \$170,698 | 1.0 |
| 2021 | (\$170,698) | \$170,698 | 1.0 |
| 2022 | (\$170,698) | \$170,698 | 1.0 |

The bill would amend the Health and Safety Code relating to the continuation and functions of the Texas State Board of Pharmacy (TSBP); authorizing a reduction in fees. The bill would continue TSBP for twelve years until September 1, 2029.

The bill would require the TSBP, in consultation with the Optometry Board, Texas Medical Board, Texas State Board of Podiatric Medical Examiners, State Board of Dental Examiners, State Board of Veterinary Medical Examiners, and the Texas Board of Nursing, to determine conduct that constitutes abusive prescribing patterns or practices by applicable licensees. Under the provisions of the bill, TSBP would be permitted to send electronic notification to a dispenser or a prescriber if the information submitted to the Prescription Monitoring Program (PMP) indicates harmful prescribing patterns. The bill would require a wholesale distributor to report the same information that is reported to the Automation of Reports and Consolidated Orders System of the Federal Drug Enforcement Administration to TSBP.

The bill would require TSBP to develop a policy to encourage the use of certain negotiated rulemaking and appropriate alternative dispute resolution procedures. Under the provisions of the bill, TSBP would be required to coordinate the implementation of the policy, provide training for implementation of the policy, and collect data on the effectiveness of the procedures.

The bill would permit an applicant or a licensee to assert as an affirmative defense in an administrative hearing or as a claim of defense in a judicial proceeding that a rule, regulation, policy or a penalty imposed by TSBP limits an applicant's exercise of religion or membership in an religious organization. The bill would provide exemptions to certain rules, regulations, policies, or penalties imposed by TSBP. Under the provisions of the bill, a licensee or applicant could bring an action for injunctive relief against a violation.

The bill would modify the renewal fee of a pharmacy technician based on the amount of time from the expiration of the licensee's former license. The bill would require TSBP to adopt rules relating to the continuing education requirements for pharmacy technicians.

The bill would take effect on September 1, 2017.

Methodology

This analysis assumes that TSBP would input and track wholesale pharmaceutical distributor reporting in a database. The provisions of the bill would result in a cost of \$224,793 in General Revenue in fiscal year 2018 and a cost of \$170,698 in General Revenue in fiscal year 2019 and following fiscal years. Based on the analysis of the TSBP, it is assumed the TSBP would require one additional full-time-equivalent (FTE) to implement provisions of the bill relating to reporting requirements of wholesale pharmaceutical distribution information. This would have an estimated cost to General Revenue of \$74,797 in fiscal year 2018 and \$70,702 each year thereafter. TSBP estimates one-time start up costs of \$4,095 for the additional FTE and annual costs of \$50,111 in salaries and wages for a Program Specialist III, \$18,351 in employee benefits and other payroll contribution costs, and \$2,240 for other operating expenses.

TSBP also estimates a one-time cost of \$50,000 in General Revenue in fiscal year 2018 for a database to track the additional required information from wholesale pharmaceutical distributors. In addition to the one-time costs in fiscal year 2018, TSBP estimates an ongoing operating cost of \$99,996 for the database in each fiscal year due to ongoing hosting and data support for the

wholesale pharmaceutical distribution information.

This analysis assumes that any increased cost to the TSBP, which is statutorily required to generate sufficient revenue to cover its costs of operation, would be offset by a corresponding increase in fee generated revenue by the agency.

The Comptroller of Public Accounts estimates the modification to the renewal fee of a pharmacy technician based on time elapsed since the expiration of the licensee's former license would result in a decrease of approximately \$36,000 in revenue to the General Revenue Fund per fiscal year.

The Department of Public Safety, Office of the Attorney General, State Office of Administrative Hearings, Office of Court Administration, Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing, and Texas Board of Podiatric Medical Examiners anticipate any additional work resulting from the passage of the bill could be reasonably absorbed within current resources.

Technology

The costs identified above include estimated one-time information technology costs of \$50,000 in fiscal year 2018 and ongoing costs of \$99,996 for database development to accompany the wholesale distributor reporting requirements and \$1,154 for one-time equipment for the additional FTE at TSBP.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 116 Sunset Advisory Commission, 212 Office of Court Administration,

Texas Judicial Council, 304 Comptroller of Public Accounts, 360 State Office of Administrative Hearings, 515 Board of Pharmacy, 302 Office of the Attorney General, 405 Department of Public Safety, 503 Texas Medical Board, 504 Texas State Board of Dental Examiners, 507 Texas Board of Nursing, 512 Board of Podiatric Medical Examiners, 514

Optometry Board, 578 Board of Veterinary Medical Examiners

LBB Staff: UP, EK, KCA, EH, BRi

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

May 9, 2017

TO: Honorable Charles Schwertner, Chair, Senate Committee on Health & Human Services

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB2561 by Thompson, Senfronia (Relating to the continuation and functions of the Texas

State Board of Pharmacy; authorizing a reduction in fees.), As Engrossed

Estimated Two-year Net Impact to General Revenue Related Funds for HB2561, As Engrossed: an impact of \$0 through the biennium ending August 31, 2019.

The bill would make no appropriation but could provide the legal basis for an appropriation of funds to implement the provisions of the bill.

General Revenue-Related Funds, Five-Year Impact:

| Hiscal Voar | | Probable Net Positive/(Negative) Impact to General Revenue Related Funds |
|-------------|------|---|
| | 2018 | \$0 |
| | 2019 | \$0 |
| | 2020 | \$0 |
| | 2021 | \$0 |
| | 2022 | \$0 |

| Fiscal Year Probable Savings/(Cost) from General Revenue Fund 1 | | Probable Revenue Gain/(Loss) from General Revenue Fund 1 | Change in Number of State Employees from FY 2017 |
|---|-------------|---|---|
| 2018 | (\$224,793) | \$224,793 | 1.0 |
| 2019 | (\$170,698) | \$170,698 | 1.0 |
| 2020 | (\$170,698) | \$170,698 | 1.0 |
| 2021 | (\$170,698) | \$170,698 | 1.0 |
| 2022 | (\$170,698) | \$170,698 | 1.0 |

The bill would amend the Health and Safety Code relating to the continuation and functions of the Texas State Board of Pharmacy (TSBP); authorizing a reduction in fees. The bill would continue TSBP for twelve years until September 1, 2029.

The bill would require the TSBP, in consultation with the Optometry Board, Texas Medical Board, Texas State Board of Podiatric Medical Examiners, State Board of Dental Examiners, State Board of Veterinary Medical Examiners, and the Texas Board of Nursing, to determine conduct that constitutes abusive prescribing patterns or practices by applicable licensees. Under the provisions of the bill, TSBP would be permitted to send electronic notification to a dispenser or a prescriber if the information submitted to the Prescription Monitoring Program (PMP) indicates harmful prescribing patterns. The bill would require a wholesale distributor to report the same information that is reported to the Automation of Reports and Consolidated Orders System of the Federal Drug Enforcement Administration to TSBP.

The bill would require TSBP to develop a policy to encourage the use of certain negotiated rulemaking and appropriate alternative dispute resolution procedures. Under the provisions of the bill, TSBP would be required to coordinate the implementation of the policy, provide training for implementation of the policy, and collect data on the effectiveness of the procedures.

The bill would permit an applicant or a licensee to assert as an affirmative defense in an administrative hearing or as a claim of defense in a judicial proceeding that a rule, regulation, policy or a penalty imposed by TSBP limits an applicant's exercise of religion or membership in an religious organization. The bill would provide exemptions to certain rules, regulations, policies, or penalties imposed by TSBP. Under the provisions of the bill, a licensee or applicant could bring an action for injunctive relief against a violation.

The bill would modify the renewal fee of a pharmacy technician based on the amount of time from the expiration of the licensee's former license. The bill would require TSBP to adopt rules relating to the continuing education requirements for pharmacy technicians.

The bill would take effect on September 1, 2017.

Methodology

This analysis assumes that TSBP would input and track wholesale pharmaceutical distributor reporting in a database. The provisions of the bill would result in a cost of \$224,793 in General Revenue in fiscal year 2018 and a cost of \$170,698 in General Revenue in fiscal year 2019 and following fiscal years. Based on the analysis of the TSBP, it is assumed the TSBP would require one additional full-time-equivalent (FTE) to implement provisions of the bill relating to reporting requirements of wholesale pharmaceutical distribution information. This would have an estimated cost to General Revenue of \$74,797 in fiscal year 2018 and \$70,702 each year thereafter. TSBP estimates one-time start up costs of \$4,095 for the additional FTE and annual costs of \$50,111 in salaries and wages for a Program Specialist III, \$18,351 in employee benefits and other payroll contribution costs, and \$2,240 for other operating expenses.

TSBP also estimates a one-time cost of \$50,000 in General Revenue in fiscal year 2018 for a database to track the additional required information from wholesale pharmaceutical distributors. In addition to the one-time costs in fiscal year 2018, TSBP estimates an ongoing operating cost of \$99,996 for the database in each fiscal year due to ongoing hosting and data support for the

wholesale pharmaceutical distribution information.

This analysis assumes that any increased cost to the TSBP, which is statutorily required to generate sufficient revenue to cover its costs of operation, would be offset by a corresponding increase in fee generated revenue by the agency.

The Comptroller of Public Accounts estimates the modification to the renewal fee of a pharmacy technician based on time elapsed since the expiration of the licensee's former license would result in a decrease of approximately \$36,000 in revenue to the General Revenue Fund per fiscal year.

The Department of Public Safety, Office of the Attorney General, State Office of Administrative Hearings, Office of Court Administration, Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing, and Texas Board of Podiatric Medical Examiners anticipate any additional work resulting from the passage of the bill could be reasonably absorbed within current resources.

Technology

The costs identified above include estimated one-time information technology costs of \$50,000 in fiscal year 2018 and ongoing costs of \$99,996 for database development to accompany the wholesale distributor reporting requirements and \$1,154 for one-time equipment for the additional FTE at TSBP.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 212 Office of Court Administration, Texas Judicial Council, 304

Comptroller of Public Accounts, 360 State Office of Administrative Hearings, 116 Sunset Advisory Commission, 515 Board of Pharmacy, 302 Office of the Attorney General, 405 Department of Public Safety, 503 Texas Medical Board, 504 Texas State Board of Dental Examiners, 507 Texas Board of Nursing, 512 Board of Podiatric Medical Examiners, 514

Optometry Board, 578 Board of Veterinary Medical Examiners

LBB Staff: UP, EK, KCA, EH, BRi

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

April 20, 2017

TO: Honorable Four Price, Chair, House Committee on Public Health

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB2561 by Thompson, Senfronia (Relating to the continuation and functions of the Texas State Board of Pharmacy; authorizing a reduction in fees.), Committee Report 1st House,

Substituted

Estimated Two-year Net Impact to General Revenue Related Funds for HB2561, Committee Report 1st House, Substituted: an impact of \$0 through the biennium ending August 31, 2019.

The bill would make no appropriation but could provide the legal basis for an appropriation of funds to implement the provisions of the bill.

General Revenue-Related Funds, Five-Year Impact:

| l Year | Probable Net Positive/(Negative) Impact to General Revenue Related Funds | |
|--------|---|--|
| 18 | \$0 | |
| 19 | \$0 | |
| 20 | \$0 | |
| 21 | \$0 | |
| 22 | \$0 | |
| | 1 Year 018 019 020 021 | |

| Fiscal Year | Probable Savings/(Cost) from General Revenue Fund 1 | Probable Revenue Gain/(Loss) from General Revenue Fund 1 | Change in Number of State Employees from FY 2017 |
|-------------|--|---|---|
| 2018 | (\$224,793) | \$224,793 | 1.0 |
| 2019 | (\$170,698) | \$170,698 | 1.0 |
| 2020 | (\$170,698) | \$170,698 | 1.0 |
| 2021 | (\$170,698) | \$170,698 | 1.0 |
| 2022 | (\$170,698) | \$170,698 | 1.0 |

The bill would amend the Health and Safety Code relating to the continuation and functions of the Texas State Board of Pharmacy (TSBP); authorizing a reduction in fees. The bill would continue TSBP for twelve years until September 1, 2029.

The bill would require the TSBP, in consultation with the Optometry Board, Texas Medical Board, Texas State Board of Podiatric Medical Examiners, State Board of Dental Examiners, State Board of Veterinary Medical Examiners, and the Texas Board of Nursing, to determine conduct that constitutes abusive prescribing patterns or practices by applicable licensees. Under the provisions of the bill, TSBP would be permitted to send electronic notification to a dispenser or a prescriber if the information submitted to the Prescription Monitoring Program (PMP) indicates harmful prescribing patterns. The bill would require a wholesale distributor to report the same information that is reported to the Automation of Reports and Consolidated Orders System of the Federal Drug Enforcement Administration to TSBP.

The bill would require TSBP to develop a policy to encourage the use of certain negotiated rulemaking and appropriate alternative dispute resolution procedures. Under the provisions of the bill, TSBP would be required to coordinate the implementation of the policy, provide training for implementation of the policy, and collect data on the effectiveness of the procedures.

The bill would modify the renewal fee of a pharmacy technician based on the amount of time from the expiration of the licensee's former license. The bill would require TSBP to adopt rules relating to the continuing education requirements for pharmacy technicians.

The bill would take effect on September 1, 2017.

Methodology

This analysis assumes that TSBP would input and track wholesale pharmaceutical distributor reporting in a database. The provisions of the bill would result in a cost of \$224,793 in General Revenue in fiscal year 2018 and a cost of \$170,698 in General Revenue in fiscal year 2019 and following fiscal years. Based on the analysis of the TSBP, it is assumed the TSBP would require one additional full-time-equivalent (FTE) to implement provisions of the bill relating to reporting requirements of wholesale pharmaceutical distribution information. This would have an estimated cost to General Revenue of \$74,797 in fiscal year 2018 and \$70,702 each year thereafter. TSBP estimates one-time start up costs of \$4,095 for the additional FTE and annual costs of \$50,111 in salaries and wages for a Program Specialist III, \$18,351 in employee benefits and other payroll contribution costs, and \$2,240 for other operating expenses.

TSBP also estimates a one-time cost of \$50,000 in General Revenue in fiscal year 2018 for a database to track the additional required information from wholesale pharmaceutical distributors. In addition to the one-time costs in fiscal year 2018, TSBP estimates an ongoing operating cost of \$99,996 for the database in each fiscal year due to ongoing hosting and data support for the wholesale pharmaceutical distribution information.

This analysis assumes that any increased cost to the TSBP, which is statutorily required to generate sufficient revenue to cover its costs of operation, would be offset by a corresponding increase in fee generated revenue by the agency.

The Comptroller of Public Accounts estimates the modification to the renewal fee of a pharmacy technician based on time elapsed since the expiration of the licensee's former license would result

in a decrease of approximately \$36,000 in revenue to the General Revenue Fund per fiscal year.

The Department of Public Safety, Office of the Attorney General, State Office of Administrative Hearings, Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing, and Texas Board of Podiatric Medical Examiners anticipate any additional work resulting from the passage of the bill could be reasonably absorbed within current resources.

Technology

The costs identified above include estimated one-time information technology costs of \$50,000 in fiscal year 2018 and ongoing costs of \$99,996 for database development to accompany the wholesale distributor reporting requirements and \$1,154 for one-time equipment for the additional FTE at TSBP.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 116 Sunset Advisory Commission, 515 Board of Pharmacy, 302 Office of

the Attorney General, 304 Comptroller of Public Accounts, 360 State Office of Administrative Hearings, 405 Department of Public Safety, 503 Texas Medical Board, 504 Texas State Board of Dental Examiners, 507 Texas Board of Nursing, 512 Board of Podiatric Medical Examiners, 514

Optometry Board, 578 Board of Veterinary Medical Examiners

LBB Staff: UP, EK, KCA, EH, BRi

FISCAL NOTE, 85TH LEGISLATIVE REGULAR SESSION

April 2, 2017

TO: Honorable Four Price, Chair, House Committee on Public Health

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: HB2561 by Thompson, Senfronia (Relating to the continuation and functions of the Texas State Board of Pharmacy; authorizing a reduction in fees.), As Introduced

Estimated Two-year Net Impact to General Revenue Related Funds for HB2561, As Introduced: an impact of \$0 through the biennium ending August 31, 2019.

The bill would make no appropriation but could provide the legal basis for an appropriation of funds to implement the provisions of the bill.

General Revenue-Related Funds, Five-Year Impact:

| Fiscal Ye | Probable Net Positive/(Negative) Impact to General Revenue Related Funds | |
|-----------|---|--|
| 2018 | \$0 | |
| 2019 | \$0 | |
| 2020 | \$0 | |
| 2021 | \$0 | |
| 2022 | \$0 | |

| Fiscal Year | Probable Savings/(Cost) from General Revenue Fund 1 | Probable Revenue Gain/(Loss) from General Revenue Fund 1 | Change in Number of State Employees from FY 2017 |
|-------------|--|---|---|
| 2018 | (\$224,793) | \$224,793 | 1.0 |
| 2019 | (\$170,698) | \$170,698 | 1.0 |
| 2020 | (\$170,698) | \$170,698 | 1.0 |
| 2021 | (\$170,698) | \$170,698 | 1.0 |
| 2022 | (\$170,698) | \$170,698 | 1.0 |

The bill would amend the Health and Safety Code relating to the continuation and functions of the Texas State Board of Pharmacy (TSBP); authorizing a reduction in fees. The bill would continue TSBP for twelve years until September 1, 2029.

The bill would require the TSBP, in consultation with the Optometry Board, Texas Medical Board, Texas State Board of Podiatric Medical Examiners, State Board of Dental Examiners, State Board of Veterinary Medical Examiners, and the Texas Board of Nursing, to determine conduct that constitutes abusive prescribing patterns or practices by applicable licensees. Under the provisions of the bill, TSBP would be permitted to send electronic notification to a dispenser or a prescriber if the information submitted to the Prescription Monitoring Program (PMP) indicates harmful prescribing patterns. The bill would require a wholesale pharmaceutical distributor to report to TSBP the sale of a controlled substance made by the distributor to a person in the state. TSBP would be required to include this information in the PMP.

The bill would require TSBP to develop a policy to encourage the use of certain negotiated rulemaking and appropriate alternative dispute resolution procedures. Under the provisions of the bill, TSBP would be required to coordinate the implementation of the policy, provide training for implementation of the policy, and collect data on the effectiveness of the procedures.

The bill would modify the renewal fee of a pharmacy technician based on the amount of time from the expiration of the licensee's former license. The bill would require TSBP to adopt rules relating to the continuing education requirements for pharmacy technicians.

The bill would take effect on September 1, 2017.

Methodology

The provisions of the bill would result in a cost of \$224,793 in General Revenue in fiscal year 2018 and a cost of \$170,698 in General Revenue in fiscal year 2019 and following fiscal years. Based on the analysis of the TSBP, it is assumed the TSBP would require one additional full-time-equivalent (FTE) to implement provisions of the bill relating to reporting requirements of wholesale pharmaceutical distribution information to the PMP. This would have an estimated cost to General Revenue of \$74,797 in fiscal year 2018 and \$70,702 each year thereafter. TSBP estimates one-time start up costs of \$4,095 for the additional FTE and annual costs of \$50,111 in salaries and wages for a Program Specialist III, \$18,351 in employee benefits and other payroll contribution costs, and \$2,240 for other operating expenses.

TSBP also estimates a one-time cost of \$50,000 in General Revenue in fiscal year 2018 for modifications to the PMP to accommodate the additional required information for wholesale pharmaceutical distributors. In addition to the one-time costs in fiscal year 2018, TSBP estimates an ongoing operating cost of \$99,996 for the PMP in each fiscal year due to ongoing hosting and data support for the wholesale pharmaceutical distribution information.

This analysis assumes that any increased cost to the TSBP, which is statutorily required to generate sufficient revenue to cover its costs of operation, would be offset by a corresponding increase in fee generated revenue by the agency and other regulatory agencies whose licensees are required to access the PMP, including the Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing and the Board of Podiatric Medical Examiners.

The Comptroller of Public Accounts estimates the modification to the renewal fee of a pharmacy technician based on time elapsed since the expiration of the licensee's former license would result in a decrease of approximately \$36,000 in revenue to the General Revenue Fund per fiscal year.

The Department of Public Safety, Office of the Attorney General, State Office of Administrative Hearings, Texas State Board of Dental Examiners, Optometry Board, Board of Veterinary Medical Examiners, Texas Medical Board, Texas Board of Nursing, and Texas Board of Podiatric Medical Examiners anticipate any additional work resulting from the passage of the bill could be reasonably absorbed within current resources.

Technology

The costs identified above include estimated one-time information technology costs of \$50,000 in fiscal year 2018 and ongoing costs of \$99,996 for PMP database changes to accompany the wholesale distributor reporting requirements and \$1,154 for one-time equipment for the additional FTE at TSBP.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 116 Sunset Advisory Commission, 302 Office of the Attorney General, 304

Comptroller of Public Accounts, 360 State Office of Administrative Hearings, 405 Department of Public Safety, 503 Texas Medical Board, 504 Texas State Board of Dental Examiners, 507 Texas Board of Nursing, 512 Board of Podiatric Medical Examiners, 514 Optometry Board, 515

Board of Pharmacy, 578 Board of Veterinary Medical Examiners

LBB Staff: UP, KCA, EH, EK, BRi